

SEP 11 2002

K021942

Attachment VIII: Summary of Safety and Effectiveness Information [510(k) Summary]

SUBMITTER: Radionics, a division of Tyco Healthcare LP  
22 Terry Ave.  
Burlington, MA 01803  
Tel.: (781) 272-1233  
Fax: (978) 663-8405  
  
Contact: Kevin J. O'Connell  
Senior Regulatory Associate

PROPRIETARY NAME: Radionics Pole Needles

COMMON OR USUAL NAME: Disposable cannula for radiofrequency electrode

CLASSIFICATION CODE: 21 C.F.R. § 882.4725

PREDICATE DEVICE: SMK Sluijter-Mehta Cannulae, RF Pole, Pole and Flexible Needles, K870028;  
RSM-C, Sluijter-Mehta Cannula, K963577  
Radionics Disposable RF Cannulae (SC-C, RFK-DB, RFK-DS), K980430

INTENDED USE: A Pole Needle is an injection needle, which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. The nerve is localized either by using electrical stimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic or a radiofrequency lesion may be made.

DESCRIPTION: There are four types of needles: SMK Sluijter-Mehta Cannulae, RF Pole, Pole and Flexible Needles.  
SMK Cannulae is used in radiofrequency (RF) lesion procedures for the relief of pain. The device allows a injection of local anesthetic to relieve the pain of RF. A SMK-TC electrode is then placed into the cannulae to create the lesion. The length of the cannula is insulated except for a section of the tip. The RF energy is then transferred from the electrode through this uninsulated portion which heats the surrounding tissue to create a lesion.  
RF Pole is used for percutaneous facet denervations. The device consists of a shaft of hypodermic tubing which is insulated except for 5mm at the tip. Plastic tubing and an electrical

lead are unitized in a single flexible leader portion which connects to the shaft. The lead is insulated and feed through the plastic tube. A Luer hub on the tubing allows injection of local anesthetic. The needle can be connected to a Radionics generator for stimulation and lesioning. The RF pole does not allow for temperature monitoring.

Pole is used for percutaneous stimulation and injection. The design of the pole is similar to the RF pole except for the exposed tip. Only the beveled surface, 1mm, is uninsulated.

The pole is intended to be connected to a stimulus generator.

Flexible Injection Needle is used for prognostic block injections of local anesthetics or injection of contrast media. The device consists of hypodermic tubing attached to PVC tubing. The needle has no electrical connection. The tubing has a Luer hub to allow the injection with a syringe at a more remote position from the needles field.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Radionics, Inc., A Division of Tyco Healthcare LP  
Kevin J. O'Connell  
Senior Regulatory Associate  
22 Terry Avenue  
Burlington, Massachusetts 01803

SEP 11 2002

Re: K021942

Trade/Device Name: Radionics Pole Needles  
Regulation Number: 882.4725; 882.4400  
Regulation Name: Probe, radiofrequency lesion; generator, lesion, radiofrequency  
Regulatory Class: Class II  
Product Code: GXI; GXD  
Dated: June 12, 2002  
Received: June 13, 2002

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

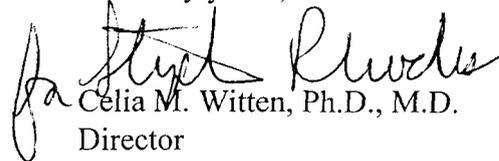
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Kevin J. O’Connell

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

2.0 ODE Indications Statement:

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510(k) Number (if known): K021942

Device Name: Radionics Pole Needles

A Pole Needle is an injection needle, which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. The nerve is localized either by using electrical stimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic or a radiofrequency lesion may be made.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K021942

PRESCRIPTION USE

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)